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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,615	02/04/1999	JAMES P. HOEFFLER	INVIT1100-1	5087

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/245,615	HOEFFLER ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-37,39,40,51,52,54-56 and 58-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-37, 39-40, 51-52, 54-56, 58-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicants' response to the non-final office action mailed 17 November 2005 is acknowledged (Paper filed 5/17/06). In the amendment filed therein claims 1-30, 38, 41-50, 53 and 57 were cancelled. Claim 67 was modified. New claims 74-80 were added. Currently claims 31-37, 39-40, 51-52, 54-56, and 58-80 are pending and under consideration.

2. Rejections and/or Objections of record not reiterated below have been withdrawn.

NEW GROUNDS OF REJECTIONS

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. The use of the trademarks has been noted in this application. (.i.e. TWEEN-page 40). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Sequence Non-Compliance

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

The specification (for example see page 24, line 22 – Phe-His-His-Thr-Thr) recites sequences but the actual sequence identification numbers are not included. Please provide the appropriate sequence identification numbers in order to comply with the sequence rules.

Applicant is given THREE MONTHS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 74-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 74, 75, 77, and 78 recite microarrays comprising 48 or 90 different antibody "preparations". This is vague and indefinite because is not clear if Applicant intends to claim a single antibody generated from multiple preparations or different antibodies with diverse binding specificities. It is suggested that the term "preparations" is removed form the claim language for clarity. Appropriate correction is required.

B. In claims 76 and 79 the microaarray comprises a collection of antibodies that recognize (bind) a set of 1000 human antigens. This is vague and indefinite because it is not clear if the antibodies actually "bind" the set of 1000 human antigens. In other words what is meant by antibody *recognition*? Further, will each antibody bind a single antigen from the set of 1000 human antigens or is each antibody required to bind/recognize all of the 1000 human antigens in the set? As recited the metes and bound of the claim cannot be determined. Please clarify.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 74-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to microarray/kit configurations comprising specific antibody embodiments of 48 different antibodies or 90 different antibodies and/or a collection of antibodies recognizing 1000 human antigens. However, support for the specific claimed embodiments is not found in the disclosure. Accordingly, the limitations are deemed new matter. Applicant is invited to show support for the newly added claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 37, 55, 56, 58, 59, 63, 64 and 70-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67).

Shalon et al. teach microarrays with immobilized reagents. The immobilized reagents include antibodies and antibody fragments that are dispensed on selected array positions. See abstract, page 11 lines 15-24, and page 31 lines 32-35, for example.

The discrete positions on the microarray are spaced apart (spatially addressable) on the solid support. See page 5 line 33, page 6 line 2, page 7 line 26-27. The source (cell line or cell type) of the antibodies at each discrete location is known (claim 55). See page 12 line 32 through page 13 line 2.

In one embodiment the microarray is treated to reduce non-specific binding with a polycationic polymer. See page 7 lines 30-32. The microarray has reagents (antibodies) spotted in discrete positions between 0.01 nanoliters and 100 nanoliters. See page 6 lines 8-10. The microarray also comprises regions from 100 locations per square centimeter to 1000 locations per square centimeter (reading on claim 64 and 73). Page 12 lines 3-9.

Shalon et al. differ from the instant invention in not specifically teaching that the antigen specificity of the antibodies is unknown.

However, Schuh et al. disclose ELISA-microtiter procedures involving the identification of monoclonal antibody specificity (antigen binding) at an early stage. See abstract. The antibodies are absorbed to microtiter wells and incubated with a labeled antigen preparation (such as a biotinylated cell lystate). See page 61 1st column. In one embodiment, two results are compared to identify the different cell lystates employed. See page 63 2nd column. The method was utilized to characterize monoclonal antibodies against both soluble proteins from mouse CIq, human CIq (antibodies recognizing proteins of a first species), and membrane determinants (like human pan T cells CD5 and CD7).

The major advantages of the screening technique are (i) the use of non-radioactive label resulting in an easy and time-saving procedure, (ii) the possibility of quantitating the amount of captured and detached antigen by ELISA, (iii) the procedure requires only a minimal amount of antigen, (iv) the procedure can be used with unpurified antibodies of all isotypes, (v) a high signal to noise ratio, and (vi) the possibility of detecting SDS-sensitive epitopes and of using crude antigen preparations. See abstract.

It would have been obvious to one of ordinary skill in the art to employ antibodies with unknown antigen specificity as taught by Schuh et al. in the microarray of Shalon et al. because Schuh et al. taught that this procedure had several advantages, including (i) the use of non-radioactive label resulting in an easy and time-saving procedure, (ii) the possibility of quantitating the amount of captured and detached antigen by ELISA, (iii) the procedure requires only a minimal amount of antigen, (iv) the procedure can be used with unpurified antibodies of all isotypes, (v) a high signal to noise ratio, and (vi) the possibility of detecting SDS-sensitive epitopes and of using crude antigen preparations. See abstract.

One of ordinary skill in the art would have been motivated to test antibodies of unknown antigen specificity in order to rapidly and simply identify antibody specificity at an early stage. See Schuh et al. page 59-60 – Introduction.

II. Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) as applied to claims 37, 55, 58, 59, 63, 64 and 70-73 above, and further in view of Ragg and Whitlow (FASEB, Vol.9, January 1995, pages 73-80).

Please see previous discussion of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) as set forth above.

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) differ from the instant invention in not teaching antibody fragments such as single chain/stranded recombinant antibody compositions.

However, Raag and Whitlow disclose single chain recombinant antibody fragments (sFv) consisting of only the variable light chain (VL) and variable heavy chain (VH) domains covalently linked by a polypeptide linker. Because the single chain recombinant antibody fragments are small they have rapid pharmacokinetics and tumor penetration in vivo. See abstract. These single chain recombinant antibody fragments are derived from the antigen-binding domain of antibodies and are useful in any molecular recognition or binding application. See page 74 2nd column 2nd paragraph. SFv's are disclosed as tine reducers in ELISA applications. See page 74 2nd column middle of the 3rd paragraph.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use antibody fragments like recombinant single chain/stranded antibodies (sFv) as taught by Raag and Whitlow in the microarray of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) to produce arrays to perform multiple sample analysis in the rapid detection systems because Raag and Whitlow taught that sFv's were small allowing for rapid penetration (abstract), useful in any antibody application (page 74 2nd column 2nd paragraph), and reduced time in ELISA procedures page 74 2nd column middle of the 3rd paragraph.

III. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Kohler et al. (Nature, 256, August 7, 1975, pages 495-497).

Please see previous discussion of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) as set forth above.

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) differ from the instant invention in not teaching that the source of the antibodies is from a known hybridoma cell line.

However, Kohler et al. teach antibody production from a known hybridoma cell (tissue culture cell lines made from fused myeloma and spleen cells from an immunized donor). Kohler et al. disclose that the production of antibodies via hybridoma is a satisfactory source of monoclonal antibodies of predefined specificity.

The cells are versatile allowing for antibody production from different origins, can be grown in massive quantity, provide specific antibodies, and could prove valuable for medical and industrial utility. Page 495 1st paragraph and page 497 2nd column last paragraph. The specification teaches that the reference of Kohler et al. teaches hybridoma procedures on page 8 lines 13-19.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize hybridoma cells to produce antibodies as taught by Kohler et al. in the antibody microarray of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) because Kohler et al. taught that hybridoma cells are versatile allowing for antibody production from different origins, can be grown in massive quantity, provide specific antibodies, and could prove valuable for medical and industrial utility. Page 495 1st paragraph and page 497 2nd column last paragraph.

With respect to claims 74-80, it is noted that priority to 2/4/98 has not been granted because support for the claims has not been exemplified in the originally filed application. Accordingly the claims have been given a priority date of 5/17/06 (the date the claims were filed) for prior art rejections. Applicant is invited to show support for claims 74-80.

IV. Claims 77-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) as applied to claims 37, 55, 58, 59, 63, 64 and 70-73 above, and further in view of Dolores J. Cahill (Journal of Immunological Methods, 250, 2001m pages 81-91).

Please see previous discussion of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) as set forth above.

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) differ from the instant invention in not teaching the utility of a plurality/collection of antibody preparations (48 and 90) wherein the antibodies recognize a set of 1000 human antigens.

Cahill teach protein and antibody arrays and their utility in medical applications. See abstract. Antibody arrays are disclosed to be useful in the detection of proteins, the level of expression of proteins, and the correlation of protein expression in normal versus tumor (disease) tissue. See page 81 2nd column. Antibody arrays provide high throughput approaches, which allow for the generation and arraying of thousands of protein and antibodies. See page 83 2nd column – last paragraph.

Theses arrays can screen thousands of proteins and are highly economical because they use small amounts of the specimens and reagents. See page 89 2nd column. Arrays are versatile in the biomedical research and clinical medicine. See page 90 1st column.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a collection of antibody compositions (48, 90 or more different antibodies) to bind a set of 1000 antigens as taught by Cahill in the microarrays of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) because Cahill taught antibody arrays are useful in the detection of proteins, the level of expression of proteins, and the correlation of protein expression in normal versus tumor (disease) tissue. See page 81 2nd column. Antibody arrays provide high throughput approaches, which allow for the generation and arraying of thousands of protein and antibodies. See page 83 2nd column – last paragraph. Theses arrays can screen thousands of proteins and are highly economical because they use small amounts of the specimens and reagents. See page 89 2nd column.

V. Claims 31-33, 36, 51-52, 54, 60-61 and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879).

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) is set forth above. Specifically, Shalon et al. disclose antibodies immobilized on microarrays while Schuh et al. teach the utility of wherein the antigen specificity is unknown with labeled cell lysates.

With respect to newly added claims 67-69, it is noted that Schuh et al. disclose a second reagent (peroxidase (HRP)-labeled avidin) for labeling a biotinylated cell lysate on page 61 2nd column. Both avidin and biotin are detectable labels as required by claims 67 and 68. Further, Schuh et al. disclose the use of multiple solid surfaces coated with a plurality of antibodies. These surfaces include microtiter plates, beads, and nitrocellulose membranes. For example, see pages 61-62.

However, the references fail to teach the reagents as a kit. Kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay microarray and reagents as taught by Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

VI. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) as applied to claims 31-33, 36, 51-52, 54, 60-61 and 67-69 above, and further in view of Ragg and Whitlow (FASEB, Vol.9, January 1995, pages 73-80).

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) is set forth above.

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) differ from the instant invention in not teaching antibody fragments such as single chain/stranded recombinant antibody compositions.

However, Raag and Whitlow disclose single chain recombinant antibody fragments (sFv) consisting of only the variable light chain (VL) and variable heavy chain (VH) domains covalently linked by a polypeptide linker.

Because the single chain recombinant antibody fragments are small they have rapid pharmacokinetics and tumor penetration in vivo. See abstract. These single chain recombinant antibody fragments are derived from the antigen-binding domain of antibodies and are useful in any molecular recognition or binding application. See page 74 2nd column 2nd paragraph.

SFv's are disclosed as tine reducers in ELISA applications. See page 74 2nd column middle of the 3rd paragraph.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use antibody fragments like recombinant single chain/stranded antibodies (sFv) as taught by Raag and Whitlow in the microarray of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) to produce arrays to perform multiple sample analysis in the rapid detection systems because Raag and Whitlow taught that sFv's were small allowing for rapid penetration (abstract), useful in any antibody application (page 74 2nd column 2nd paragraph), and reduced time in ELISA procedures page 74 2nd column middle of the 3rd paragraph.

VII. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) as applied to claims 31-33, 36, 51-52, 54, 60-61 and 67-69 above, and further in view of Kohler et al. (Nature, 256, August 7, 1975, pages 495-497).

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) is set forth above.

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) differ from the instant invention in not teaching that the source of the antibodies is from a known hybridoma cell line.

However, Kohler et al. teach antibody production from a known hybridoma cell (tissue culture cell lines made from fused myeloma and spleen cells from an immunized donor). Kohler et al. disclose that the production of antibodies via hybridoma is a satisfactory source of monoclonal antibodies of predefined specificity.

The cells are versatile allowing for antibody production from different origins, can be grown in massive quantity, provide specific antibodies, and could prove valuable for medical and industrial utility. Page 495 1st paragraph and page 497 2nd column last paragraph. The specification teaches that the reference of Kohler et al. teaches hybridoma procedures on page 8 lines 13-19.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize hybridoma cells to produce antibodies as taught by Kohler et al. in the antibody microarray of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) because Kohler et al. taught that hybridoma cells are versatile allowing for antibody production from different origins, can be grown in massive quantity, provide specific antibodies, and could prove valuable for medical and industrial utility. Page 495 1st paragraph and page 497 2nd column last paragraph.

With respect to claims 74-80, it is noted that priority to 2/4/98 has not been granted because support for the claims has not been exemplified in the originally filed application. Accordingly the claims have been given a priority date of 5/17/06 (the date the claims were filed) for prior art rejections. Applicant is invited to show support for claims 74-80.

VIII. Claims 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) as applied to claims 31-33, 36, 51-52, 54, 60-61 and 67-69 above, and further in view of Dolores J. Cahill (Journal of Immunological Methods, 250, 2001m pages 81-91).

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) is set forth above.

Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) differ from the instant invention in not teaching the utility of a plurality/collection of antibody preparations (48 and 90) wherein the antibodies recognize a set of 1000 human antigens.

However, Cahill teach protein and antibody arrays and their utility in medical applications. See abstract. Antibody arrays are disclosed to be useful in the detection of proteins, the level of expression of proteins, and the correlation of protein expression in normal versus tumor (disease) tissue. See page 81 2nd column. Antibody arrays provide high throughput approaches, which allow for the generation and arraying of thousands of protein and antibodies. See page 83 2nd column – last paragraph.

Theses arrays can screen thousands of proteins and are highly economical because they use small amounts of the specimens and reagents. See page 89 2nd column. Arrays are versatile in the biomedical research and clinical medicine. See page 90 1st column.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a collection of antibody compositions (48, 90 or more different antibodies) to bind a set of 1000 antigens as taught by Cahill in the microarray kits of Shalon et al. (WO 95/35505) in view of Schuh et al. (Journal of Immunological Methods, Vol.152, No.1, 1992, pages 59-67) and further in view of Foster et al. (U.S.Patent#4,444,879) because Cahill taught antibody arrays are useful in the detection of proteins, the level of expression of proteins, and the correlation of protein expression in normal versus tumor (disease) tissue. See page 81 2nd column. Antibody arrays provide high throughput approaches, which allow for the generation and arraying of thousands of protein and antibodies. See page 83 2nd column – last paragraph. Theses arrays can screen thousands of proteins and are highly economical because they use small amounts of the specimens and reagents. See page 89 2nd column.

Response to Arguments

Applicants contend that there is no reasonable expectation of success in the combination of Shalon et al. with Schuh et al. because methods are incompatible. This argument was carefully considered but not found persuasive because the claims are not directed to the methods of employing the microarrays (products). There is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillion, 919 F.2d 688, 696, 16 USPQ 2d 1897, 1904 (Fed Cir 1990) (in banc), cert. denied, 111S. Ct. 1682 (1991).

An obvious rejection is proper under Dillon so long as the prior art suggests a reason or provides motivation to make the claimed invention, even where the reason or motivation is different from that discovered by Applicant. In this case, it would have been obvious to one of ordinary skill in the art to employ antibodies with unknown antigen specificity as taught by Schuh et al. in the microarray of Shalon et al. because Schuh et al. taught that this procedure had several advantages, including (i) the use of non-radioactive label resulting in an easy and time-saving procedure, (ii) the possibility of quantitating the amount of captured and detached antigen by ELISA, (iii) the procedure requires only a minimal amount of antigen, (iv) the procedure can be used with unpurified antibodies of all isotypes, (v) a high signal to noise ratio, and (vi) the possibility of detecting SDS-sensitive epitopes and of using crude antigen preparations. See abstract. One of ordinary skill in the art would have been motivated to test antibodies of unknown antigen specificity in order to rapidly and simply identify antibody specificity at an early stage. See Schuh et al. page 59-60 – Introduction.

Applicant argues that Shalon et al. do not teach antibody immobilization because the examples are all directed to nucleic acid arrays. This argument was carefully considered but not found persuasive because Shalon et al. disclose that their genetic applications (nucleic acid) can be used with antibodies. See page 31 line 32 through page 32 line 4, for example. Further, a reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507 (CCPA 1966). In re Chapman, 357 F.2d 418, 148 USPQ 711 (CCPA 1966).

Applicant contends that Shalon et al. do not teach the immobilization of antibodies that retain their ability to bind antigens. This argument was carefully considered but not found persuasive because Shalon et al. are is cited in combination with Schuh et al. Schuh et al. disclose this limitation on pages 61-65. While a deficiency in a reference may overcome a rejection under 35 USC 103, a reference is not overcome by pointing out that a reference lacks a teaching for which other references are relied. In re Lyons, 364 f.2d 1005, 150 USPQ 741, 746 (CCPA 1966).

Applicant contends that the methods of Schuh et al. and Shalon et al. are not combinable because they are diverse. Specifically, Schuh et al. employ Western blot procedures, while Shalon et al. employ gel detection after elution. This argument was carefully considered but not found persuasive because the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. See, In re Bent, 52 CCPA 850, 144 USPQ 28 (1964); In re Nievelt, 179 USPQ 224 (CCPA 1973). Both Schuh et al. and Shalon et al. disclose reagent coated microarrays (microtiter plates) and are therefore analogous and combinable.

Applicant argues that the instant invention is commercially successful and meets a long-felt need. This argument was carefully considered but not found persuasive because evidence of commercial success is not persuasive of patentability when the claimed invention would flow logically from the teaching of the prior art. In re Crokett et al. (CCPA 1960) 279 F2d 274, 125 USPQ 186.

With respect to the remaining rejections under 35 USC 103, Applicant argues that the combination of Shalon et al. and Schuh et al. do not make the instant invention obvious. Therefore the remaining rejections under 35 USC 103 are not obvious. This argument has been carefully considered but not found persuasive. The combination of Shalon et al. and Schuh et al. has been addressed a priori and is maintained. Accordingly, the remaining rejections under 35 USC 103 are also maintained.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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